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510(k) SUMMARY
(Per 21 CFR 807.92)

MAY 10 2011

General Company Information

Name: Tornier, Inc.

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Tornier, Inc.

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Date Prepared April 15, 2010

General Device Information

Product Name: Tornier® BioFiber Scaffold

Classification: "Absorbable Surgical Mesh"
Product code: FTL - Class II

Predicate Device

Tepha, Inc.	TephaFLEX™ Surgical Mesh [510(k) Number K070894]
Tornier, Inc.	Tornier® Surgical Mesh [510(k) Number K093799]

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Description

Tornier® BioFiber Scaffold is a bi-layer, synthetic absorbable reinforced woven fabric made from poly(4-hydroxybutyrate) fibers. The construction permits the mesh to be cut into any desired shape or size without unraveling. The device is supplied sterile, for single-patient use for the reinforcement of soft tissue where weakness exists.

Intended Use (Indications)

Tornier® BioFiber Scaffold is intended for use where temporary wound support is required to reinforce soft tissues where weakness exists or for the repair of fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Tornier® BioFiber Scaffold is intended for reinforcement of soft tissues, in conjunction with sutures and/or suture anchors during tendon repair surgery; including the reinforcement of rotator cuff, patellar, Achilles, biceps and quadriceps tendons.

Tornier® Surgical Mesh is not intended for use as a replacement for normal body structures or to provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide mechanical strength for the tendon repair.

Substantial Equivalence

This submission supports the position that the Tornier™ BioFiber Scaffold is substantially equivalent to previously cleared devices, including those listed above. A number of predicate devices list the same range of clinical uses. Scientific evidence of substantial equivalence has been previously submitted to FDA. The device that is the subject of this submission is exactly the same device as the Tornier predicate device.

Conclusions

Tornier, Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the Tornier® Surgical Mesh. The materials from which the Tornier device is fabricated have an established history of use, and the device has been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Tornier, Inc.
% Mr. Howard L. Schrayer
100 Cummings Center – Suite 444C
Beverly, Massachusetts 015

MAY 10 2011

Re: K102788
Trade/Device Name: Tornier® BioFiber Scaffold
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: April 15, 2011
Received: April 18, 2011

Dear Mr. Schrayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K102788

Device Name: Tornier® BioFiber Scaffold

Indications For Use:

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Prescription Use ____X_____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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